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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/402,405	10/04/99	GILVARG C	PRIN-0064

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EXAMINER	
LEARY,L	
ART UNIT	**PAPER NUMBER**
1623	6

DATE MAILED: 11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/402,405	Applicant(s) Charles Gilvarg
	Examiner Louise Leary	Group Art Unit 1623

☒ Responsive to communication(s) filed on *Aug 26, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *4 and 5* is/are allowed.

☒ Claim(s) *1-3* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-5 are pending in this application.

2. Applicant's arguments filed 8-26-2000 have been fully considered but they are not persuasive.

A) *Rejection of claims 1-3 under 35 USC 102(b) as being anticipated by Sugiyama et al (US Patent Number 4,551,272).*

In regards to *Sugiyama et al (US Patent Number 4,551,272),* applicants have argued that "Although this patent mentions that the enzyme, carboxypeptidase A, is found in the pancreas, nowhere does this patent teach or suggest how levels of the enzyme specifically correlate with types of pancreatic disease. Therefore, contrary to the Examiner's suggestion, this patent does not teach or suggest the method of claim 3 which is a method of diagnosing a specific form of pancreatic disease. The mere fact that the enzyme can be measured is not sufficient teaching for correlation of levels with a disease.", it is first noted that the 35 USC 102(b) statue list several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of this US Patent application. Also, the prior art need not be identical to the claimed invention but will bar patentability if it is an obvious variant thereof. *In re Foster*, 343 F.2d 980, 145 USPQ 166 (CCPA 1966). In addition, regarding a method of diagnosing acute pancreatitis in a patient using the method of measuring carboxypeptidase A levels in a patient's fluid as claimed, Sugiyama et al disclose that the enzyme carboxypeptidase A (CP-A) "CP-A is a

protein-decomposing enzyme which is found in the pancreas and the blood serum. The activity of CP-A depends on the disease which is present and its extent. Accordingly, by measuring the activity of the CP-A, the extent to which a disease has spread can be measured." See column 1, lines 1-51. The fact that the enzyme can be measured is sufficient teaching for correlation of CP-A measurements and levels of disease. Thus, Sugiyama et al disclose or provide clear guidance which anticipates all limitations claimed in instant claim 3.

With respect to applicants arguments that "...nowhere does this patent teach or suggest a method for either measuring carboxypeptidase A or a method for enhancing sensitivity and specificity of an assay by measuring enzyme activity in the presence of a "specific inhibitor" of the enzyme being measured. Careful review of this patent failed to reveal such teaching of an inhibitor of carboxypeptidase A that is used at the same time as a substrate for the enzyme. This patent teaches only that a termination solution of 6.5 mM sodium periodate, which is not a specific inhibitor of carboxypeptidase A, can be used to create a blank. The present method is based on use of a specific inhibitor of the enzyme in conjunction with a substrate. Without teaching of use of a specific carboxypeptidase A inhibitor, Sugiyama et al fails to teach the limitations of the claims as filed. Therefore, this patent cannot anticipate the instant claims." Sugiyama et al specifically disclose a method for determining the activity of CP-A in the presence and absence of a reaction inhibitor. Sugiyama et al disclose that "...a reaction termination solution..." was added to the reaction mixture. See column 6, lines 23-68. It is noted that the examiner disagrees with applicant's assertion that the reaction stop solution is not specific for the

enzyme CP-A because Sugiyama et al disclose the reaction stop solution was used in an assay for determining CP-A activity. Again, the reaction stop solution was specific for CP-A activity as noted by Sugiyama et al. Note column 6, lines 23-68. Hence, Sugiyama et al addresses the "specific inhibitor" claim limitation in instant claims 1-3. The rejection claims 1-3 under 35 USC 102 (b) has been maintained in view of the Sugiyama et al disclosure.

B) *Rejection of claims 1-3 under 35 USC 102(b) as anticipated by Sugiyama et al (US Patent 4,432,896)*

Noted that the 35 USC 102(b) statue list several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of this US Patent application. Additionally, the prior art need not be identical to the claimed invention but will bar patentability if it is an obvious variant thereof. *In re Foster*, 343 F.2d 980, 145 USPQ 166 (CCPA 1966). In regards to applicant's arguments that "Careful review of this patent reveals that nowhere does a method for either enhancing sensitivity or specificity of an enzyme assay or method for measuring carboxypeptidase A activity that is the same as that of the instant invention. Further, nowhere does this patent teach or suggest that measurement of levels of carboxypeptidase A will in any way correlate with the specific disease claimed in claim 3, acute pancreatitis.", Sugiyama et al teach or suggest a method for measuring or determining the activity of carboxypeptidase A (CP-A). See column 6, lines 23-68. The method steps and reactants set forth in the claims are disclosed or suggest by Sugiyama et al. Hence, " a method of enhancing

sensitivity and specificity of an assay measuring enzymatic activity in a sample comprising instant the steps and reactants were inherent features of the Sugiyama et al assay for determining the activity of CP-A. With respect to a method of diagnosing acute pancreatitis in a patient using the method of measuring carboxypeptidase A levels in a patient's fluid as claimed, Sugiyama et al disclose that the enzyme carboxypeptidase A (CP-A) "CP-A is a protein-decomposing enzyme which is found in the pancreas and the blood serum. The activity of CP-A depends on the disease which is present and its extent. Accordingly, by measuring the activity of the CP-A, the extent to which a disease has spread can be measured." See column 1, lines 1-51. The fact that the enzyme can be measured is sufficient teaching for correlation of CP-A measurements and levels of disease. Alternatively, Sugiyama et al disclose or provide clear guidance which anticipates all limitations claimed in instant claim 3. In view of the Sugiyama et al disclosure, the rejection of claims 1-3 under 35 USC 102 (b) has been maintained.

C). *Rejection of claims 1-3 under 35 USC 103(a)*

In response to applicant's argument that the combination of the Brown et al and Talley et al prior art references "...cannot render the claimed invention obvious", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would

have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is noted that Brown et al disclose the method steps and reactants claimed except for stating that a specific inhibitor can be present in a method step for measuring enzymatic activity in a sample which was provided by Talley disclosing that the inhibitor 2(R)-benzylsuccinic acid is specific for the enzyme carboxypeptidase (CP-A). With respect to applicant's assertion that Brown et al in combination with Talley lack motivation to combine the references, it is noted that "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1992). Talley's disclosure that the inhibitor 2(R)-benzylsuccinic acid is specific for the enzyme carboxypeptidase (CP-A) suggest the desirability of the combination of Brown et al and Talley. Brown et al disclose a method for measuring CP-A activity but does not address the use of an inhibitor, per se. Talley disclose the use of a specific compound in a specific assay method. More specifically, Talley disclose "...the activity of carboxypeptidase A has been found to be strongly inhibited by 2(R)-benzylsuccinic acid." Hence, Brown et al in combination with Talley renders the methods of instant claims 1-3 obvious to one having ordinary skill in this art at the time this invention was made. In view of the combined prior art disclosures, the rejection under 35 USC 103 (a) has been maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication should be directed to Louise Leary at telephone number (703) 308-3533.

LOUISE N. LEARY
PRIMARY EXAMINER

November 20, 2000